

# The effect of diabetes education tailored to nurses in psychiatry

<b>Submission date</b> 19/09/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 02/10/2019	<b>Overall study status</b> Completed	
<b>Last Edited</b> 19/11/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Diabetes is more prevalent and insufficient treated among individuals with severe mental illness, and it is an important risk for heart diseases and premature death. On average individuals with severe mental illness die 15-20 years earlier than people without severe mental illness. The aim of the present study is to develop a diabetes education tailored to psychiatric nurses and investigate the effectiveness of the education to determine whether this will lead to better diabetes care among people with both severe mental illness and diabetes.

### Who can participate?

People with severe mental illness and diabetes treated in one of the eight selected psychiatric outpatient clinics are all eligible to participate.

### What does the study involve?

The study involves three consecutive days of diabetes education provided to all psychiatric nurses at four psychiatric out-patient clinics in Denmark. The effectiveness of the diabetes education is measured based on differences in quality of diabetes care in people with severe mental illness and diabetes treated at psychiatric outpatient clinics where all psychiatric nurses have participated in the diabetes education compared to psychiatric outpatient clinics where the psychiatric nurses have not participated in the diabetes education.

### What are the possible benefits and risks of participating?

**Benefits:** For the psychiatric nurses to gain more knowledge and skills in diabetes treatment. For people with severe mental illness and diabetes, participating in the study, the benefit of participating is to gain better quality of diabetes care.

There is no risk of participating in the study as there is no extra blood test or other clinical test involved in this study. All the participants are asked to complete a baseline questionnaire and four follow-up questionnaires two years after the intervention. Moreover, the participants will give the research team access to data from the Danish Health care platform (medical journals) regarding their diabetes treatment and treatment of the psychiatric disease(s). The data will be stored in accordance with the GDPR regulations.

Where is the study run from?  
Steno Diabetes Center Copenhagen, Denmark

When is the study starting and how long is it expected to run for?  
April 2018 to March 2022

Who is funding the study?  
1. The education department of Steno Diabetes Center Copenhagen  
2. Jascha Foundation

Who is the main contact?  
Lenette Knudsen  
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## Contact information

**Type(s)**  
Public

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

Nil known

# Study information

## Scientific Title

The effectiveness of Diabetes Education tailored to nurses in PSYchiatry (DEPSY): a pragmatic non-randomised controlled cluster study

## Acronym

DEPSY

## Study objectives

The overall hypothesis is that the intervention, the diabetes education, will improve indicators of quality of diabetes care measured on individuals with diabetes and severe mental illness in the intervention cluster during 12- and 24-months follow-up after the intervention.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study was submitted to ethical approval (Region Hovedstaden, Center for Sundhed, De Videnskabsetiske Komiteer, Kongens Vaenge 2, 3400 Hillerod, Denmark; +45 38 66 63 95; vek@regionh.dk) but Ethical Committee assessed the study as a quality development study and was therefore not assessed by the ethical committee

## Study design

Single-center interventional pragmatic non-randomized controlled cluster study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Diabetes and severe mental illness

## **Interventions**

The intervention is a 3-day diabetes education tailored to psychiatric nurses in psychiatric outpatient clinics. The diabetes education is provided to all nurses employed at four psychiatric outpatient clinics, approximately 70 nurses in total. The education aims to improve the quality of diabetes treatment for individuals with severe mental illness and diabetes. The overall aim of the education is to improve the nurses' diabetes knowledge and skills. The aim of the education is to provide the nurses with knowledge and skills which will give them the ability to identify and judge physical, mental and social changes for patients with severe mental illness and diabetes and support the patient in obtaining appropriate treatment of diabetes. The education is developed and conducted by the Department of Education at Steno Diabetes Center Copenhagen. The development of the intervention is based on a needs assessment lead by a team of both education and diabetes specialists (nurses, medical doctor, dietician and podiatrist) and health education researchers from the Department of Education to establish the nurses' current knowledge, skills and usual clinical practice. All nurses from the psychiatric outpatient clinics in the intervention group will participate in the intervention from February 2019 until December 2019.

The control group will receive standard of care, as provided by the Danish Health Care System which provides universal care to all.

The intervention group and control group were allocated in accordance with the regional organisation of psychiatric wards where it was possible to deliver the intervention.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Number of measurements and change in HbA1c levels collected two years prior to the intervention (baseline) and every 6 months 2 years after the intervention
2. Patient-reported outcomes measured in questionnaires collected one time before the intervention (baseline) and once every 6 months 2 years after the intervention. The patient-reported outcomes are based on the following scales SDSCA, PAID5, DAWN2 (tailored to people with both severe mental illness and diabetes), PACIC (tailored to people with both severe mental illness and diabetes), CARE (tailored to people with both severe mental illness and diabetes), WHO5 and SF36 and two new questions has been developed for the present study:  
On a scale from 1 to 10 how much does diabetes impact your everyday life?  
How relevant is it to receive diabetes-related support from your psychiatric nurse from the psychiatric outpatient clinic?

## **Secondary outcome measures**

Measured two years before the intervention and every 6 months 2 years after the intervention:

1. Change in number of measured lipids, urine albumin /creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals

2. Change in levels of lipids, urine albumin/creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals
3. Change in number of prescriptions on diabetes-related medicine (glucose-, lipids and blood pressure lowering medicine) collected from electronic patient journals
4. Change in proportion of patients screened for diabetes complications collected based on questionnaires

**Overall study start date**

01/03/2018

**Completion date**

31/03/2022

## Eligibility

**Key inclusion criteria**

1. Individuals diagnosed with diabetes and severe mental illness
2. Treated in one of the eight psychiatric outpatient clinics in the recruitment period
3. Aged  $\geq 18$  years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Two groups: Intervention group: approx. 60 Individuals  $\geq 18$  years with type 1 or type 2 diabetes and severe mental illness treated in one of the four psychiatric outpatient clinics, where the psychiatric nurses have completed the diabetes education. Control group: approx. 60 Individuals  $\geq 18$  years with type 1 or type 2 diabetes and severe mental illness treated in one of the four psychiatric outpatient clinics, where the psychiatric nurses have not received diabetes education

**Total final enrolment**

107

**Key exclusion criteria**

1. Patients without diabetes
2. Patients not in the psychiatric outpatient clinics
3. Patients who do not wish to participate

**Date of first enrolment**

30/08/2018

**Date of final enrolment**

01/06/2019

**Locations****Countries of recruitment**

Denmark

**Study participating centre****Psychiatric Outpatient Center Ballerup**

Bygning 28A

Maglevænget 2

Ballerup

Denmark

2750

**Study participating centre****Psychiatric Outpatient Center Gladsaxe**

Gladsaxe Møllevej 15, 1.sal

Søborg

Denmark

2860

**Study participating centre****Psychiatric Outpatient Center Hillerød**

Dyrehavevej 48

Hillerød

Denmark

3400

**Study participating centre****Psychiatric Outpatient Center Helsingør**

Esrumvej 143

Helsingør

Denmark

3000

**Study participating centre****Psychiatric Outpatient Center Bispebjerg-Brønshøj**

Møntmestervej 17

København NV

Denmark  
2400

**Study participating centre**

**Psychiatric Outpatient Center Frederiksberg og Vanløse**  
Nimbusparken 24  
Frederiksberg  
Denmark  
2000

**Study participating centre**

**Psychiatric Outpatient Center Indre by og Østerbro**  
Strandboulevarden 96  
København Ø  
Denmark  
2100

**Study participating centre**

**Psychiatric Outpatient Center Nørrebro**  
Griffenfeldsgade 46  
København N  
Denmark  
2200

## **Sponsor information**

**Organisation**

Steno Diabetes Center

**Sponsor details**

Niels Steensensvej 4  
Gentofte  
Denmark  
2820  
+45 (0)39 68 08 00  
SDC-FP-STENOINFO@REGIONH.DK

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.sdcc.dk/>

**ROR**

<https://ror.org/03w7awk87>

**Organisation**

Jascha Foundation

**Sponsor details**

Vedbæk stationsvej 18

Vedbæk

Denmark

2950

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**Sponsor type**

Charity

**Website**

<https://jaschafonden.dk/>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Steno Diabetes Center Copenhagen - Education Department

**Funder Name**

Jascha Foundation

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/01/2024



**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to national and regional data protection guidelines it is not possible to share the data even though the data is pseudonymised

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	528		17/11/2023	Yes	No
<a href="#">Other publications</a>	652		17/11/2023	Yes	No
<a href="#">Other publications</a>	Observational cross-sectional study	25/01/2022	17/11/2023	Yes	No
<a href="#">Results article</a>		18/11/2024	19/11/2024	Yes	No